

PATENT COOPERATION TREATY

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From the
INTERNATIONAL SEARCHING AUTHORITY

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To:

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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/IB2004/003378

International filing date (day/month/year)
15.10.2004

Priority date (day/month/year)
17.10.2003

International Patent Classification (IPC) or both national classification and IPC
A61K9/22, A61K47/38, A61P9/12

Applicant
RANBAXY LABORATORIES LIMITED

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**International application No.
PCT/IB2004/003378

IP20 Rec'd PCT/PTO 17 APR 2006

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/B2004/003378

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 18

because:

☒ the said international application, or the said claims Nos. 18 relate to the following subject matter which does not require an international preliminary examination (*specify*):

see separate sheet

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the whole application or for said claims Nos.

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form ☐ has not been furnished

☐ does not comply with the standard

the computer readable form ☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/B2004/003378

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	14-17
	No: Claims	1-13,18
Inventive step (IS)	Yes: Claims	
	No: Claims	1-18
Industrial applicability (IA)	Yes: Claims	1-17
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

PCT/IB2004/003378

AP20 Rec'd PCT/PTO 17 APR 2006**Re Item III****Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

Claim 18 relates to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of this claim (Article 34(4)(a)(I) PCT).

Re Item V**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Reference is made to the following documents:

D1: EP-A-1 293 196 (PHARMA PASS II LLC) 19 March 2003

D2: WO 97/18814 A (PFIZER RESEARCH AND DEVELOPMENT COMPANY, N.V./S.A; PFIZER LIMITED; PFI) 29 May 1997

D3: US-A-5 009 895 (LUI ET AL) 23 April 1991

2. The subject-matter of independent claims 1 and 18 is not novel (Art. 33(2) PCT) in view of prior art disclosures which can be taken from D1 and D2. Said prior art documents disclose doxazosin tablets for oral administration comprising a sustained release matrix comprising a mixture of a low viscosity and high viscosity polymer (cf. passages cited in the ISR).
3. In view of the state of the art disclosed in D1-D4 also the dependent claims 2-17 do not appear to contain any additional features which, in combination with the features of any claim to which they refer, would render the claimed subject-matter novel and inventive (Art.33(2)-(3) PCT).
- 3.1 The specific embodiments are disclosed or at least suggested by the mentioned state of the art. The sustained release matrix for doxazosin according to D1 and D2 comprise the low and high viscosity polymers in amounts falling within the claimed range. Furthermore, excipients such as surfactants, diluents, lubricants, etc. are

disclosed.

- 3.2 Although D1 and D2 may not explicitly disclose a mixture of low and high viscosity HPMC in combination with doxazosin, the use of such mixture as a sustained release matrix is known in the art and e.g. disclosed in D3. Accordingly, no inventive step can be seen in the selection of commonly known alternative mixtures of low and high viscosity polymers as a basis for the sustained release of doxazosin. None of the claimed features appears to bring a solution to any specific problem, as compared to the state of the art, which solution would involve an inventive step.
4. The subject-matter of claims 1-17 is considered to be industrially applicable and accordingly meets the requirements of Art.33(4) PCT.

Re Item VIII

Certain observations on the international application

The relative terms "*low viscosity*" and "*how viscosity*" used in claims have no well-recognised meaning and leave the reader in doubt as to the meaning of the technical features to which they refer, thereby rendering the scope of the subject-matter of said claims unclear, Article 6 PCT.